numbered 16 address whether or not the presently claimed invention is "enabled" or the "ability" to produce the claimed invention. Applicants will address those comments. However, applicants also respectfully request that the Office identify the particular requirement under 35 U.S.C. § 112, first paragraph, involved here.

The Office asserts that the specification is not directed to the claimed invention. That assertion is based upon one quote from page 1 of the specification. (Paper No. 16, at pages 3-4.) However, if one skilled in the art reads further in the specification, to pages 13 and 14 for example, applicants discuss producing viral antigens by recombinant means and disclose information encompassing the presently claimed invention. There is no requirement that an applicant must place a discussion of every embodiment of an invention on page 1 of a specification. In addition, original claim 21 indicates that expressing viral antigens from the disclosed DNA fragments is an aspect of the originally disclosed invention.

The Office also states that "applicants do not provide any demonstrable evidence suggesting that the instantly claimed restriction fragments are capable of encoding" viral antigens. (Paper No. 16, at page 4.) However, it is not applicants' burden to do so. The Office must show that the claimed invention is not enabled. There are no statements in Paper No. 16 purporting to show that the recited DNA fragments do not encode a viral antigen. Without such a showing, there is no *prima facie* case of lack of enablement.

Applicants identify that expressed viral antigens are part of their invention, as indicated above. While the Office contends that "the ability of these restriction fragments to actually encode" viral antigens is not taught (Paper No. 16 at page 4), how the applicants

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1300 I STREET, N. W.
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"teach" a particular aspect of their invention is not a controlling factor in the enablement inquiry. Applicants state in the specification at page 13, lines 12-36 and in original claim 21 that the DNA fragments can be used to express viral antigens or polypeptides. Therefore, absent some showing by the Office to the contrary, applicants need not provide further "demonstrable" proof.

The Office asserts that nucleotide sequence data and the precise coding regions "are the *sine qua non* for the expression" of viral proteins. (Paper No. 16, at page 4.) Applicants respectfully disagree. In this case, applicants present isolated restriction fragments from a larger sequence known to encode a number of proteins. In addition, applicants discuss, at page 6, lines 6-26 of the specification, how they and anyone one skilled in the art could have used available information to determine the coding regions such as the envelope protein. Since, at the time the invention was made, one skilled in the art had appropriate vectors to express DNA encoding protein sequences, they could have expressed viral antigens as indicated in the specification. Thus, there is no reason why the exact coding regions need be identified in this case.

The Office also asserts that "the specification does not teach the identification of a replication competent LAV proviral clone." (Paper No. 16, at page 5.) The Office concludes that if the identified clone is "defective ... viral antigens may not be expressed." Apparently, the Office asserts that a clone must be replication competent in order to encode any viral antigens. However, there is no evidence on the record to support such a theory.

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Furthermore, there is no evidence on the record to suggest that the disclosed clone is not replication competent.

At page 5 of Paper No. 16, the Office again asserts that applicants must disclose the viral antigens used to produce the claimed antibodies in a particular manner. Thus, the Office asks for "stable expression, recovery, and purification of viral antigens." As noted above, it is not applicants' burden to provide such evidence absent a *prima facie* showing of lack of enablement. The Office's attempts to shift the burden to applicants is improper. Rather than focusing on theoretical "caveats" that are applicable to every recombinant protein, as Paper No. 16 does on pages 5-7, a *prima facie* case of lack of enablement addresses the presently claimed invention. Here, nothing has been put forth to show that applicants' claimed invention could not have been made and used by one skilled in the art.

The Office also cites a Luciw and Dina document as alleged evidence of the state of the art at the time the invention was made. The Office should recognize, however, that portions of a patent contain statements of a persuasive nature, especially in the background wherein the patentee alleges the failures and disadvantages of the prior art. The quote from Luciw and Dina, alleging absolute novelty of their claimed invention and the inability of others to produce their claimed invention, shows that this document is attempting to be persuasive of novelty and patentability. The Office cannot properly base an analysis of the state of the art upon one persuasive representation originally included in the background of a patent application to discuss the state of the prior art.

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& DUNNER, L.L.P.
1300 I STREET, N. W.
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For these reasons, the Office has not presented a *prima facie* showing that applicants' specification does not meet the requirements of 35 U.S.C. § 112, first paragraph. Thus, applicants respectfully request the withdrawal of this rejection.

MT

Claim 23 stands rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Putney *et al.* (1986). Applicants respectfully traverse this rejection.

Applicants claim benefit of their prior application Serial No. 06/771,230 filed on August 30, 1986. As shown above, that prior application, containing the same specification as here, adequately discloses the claimed invention for purposes of 35 U.S.C. § 112, first paragraph. Putney *et al.* was published, according to the document itself, December 12, 1986. Since Putney *et al.* was not published "more than one year prior to the date of application for patent in the United States," Putney *et al.* is not "prior art " to this application. This rejection is in error and should be withdrawn.

MT

Claims 23, 32, and 33 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Luciw and Dina (U.S. Patent 5,156,949). Applicants respectfully traverse this rejection.

The cited Luciw and Dina document represents a number of earlier filing dates. Only the very first of these dates is prior to applicants' filing date in the U.S. Without the knowledge of when the particular information asserted by the Office to anticipate the claimed invention herein, i.e., Figure 5 was apparently added subsequent to the first-filed specification maturing into the Luciw and Dina document, one cannot know when that information was described.

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& DUNNER, L.L.P.
1300 I STREET, N. W.
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Furthermore, applicants priority document, GB 84 23659 filed September 19, 1984 (copy enclosed), appears to contain the same specification and claims as applicants' prior application Serial No. 06/771,230. The priority document antedates even the earliest date for Luciw and Dina. Since the prior application and the priority document adequately disclose the invention for purposes of 35 U.S.C. § 112, first paragraph, the Luciw and Dina document is not "prior art" to this application. This rejection is in error and should be withdrawn.

If there are any other fees due in connection with the filing of this Response, please charge such fees to our Deposit Account No. 06-0916. If an extension of time is required under 37 C.F.R. § 1.36 and not accounted for above, such an extension is respectfully requested and the fee should be charged to Deposit Account No. 06-0916.

Respectfully Submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Date: May 22, 1996
Encl: copy of GB 84 23659

David J. Kulik
Registration No. 36,576

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FINNEGAN, HENDERSON,
FARABOW, GARRETT
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
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